#21

distributors, or importers whose products FDA seeks to detain or ban. As previously stated, the collection of data and information under these regulations is conducted on a very infrequent basis and only as necessary.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Hours
800.55(g)	1	1	1	25	25
895.21(d) and 895.22	26	1	26	16	416
Total					441

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per	Total Annual Records	Hours per Recordkeeper	Total Hours
800.55(k)	1	1	1	20	20
Total					20

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Over the past several years, there has been an average of less than one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained. Historically, the Center for Devices and Radiological Health has had very few or no annual responses for this information collection and normally reports one response per year.

FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with one of the three firms whose devices had been detained.

Dated: March 7, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03-6230 Filed 3-14-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0319]

Agency Information Collection Activities; Announcement of OMB Approval; Blood Establishment Registration and Product Listing, Form FDA 2830

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Blood Establishment Registration and Product Listing, Form FDA 2830" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 19, 2002 (67 FR 69747), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0052. The approval expires on February 28, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: March 10, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03-6231 Filed 3-14-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E-0849]

Determination of Regulatory Review Period for Purposes of Patent Extension; VITREON; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending its determination regarding the regulatory review period for purposes of patent extension for VITREON that appeared in the **Federal Register** of December 17, 1998 (63 FR 69633). FDA is amending the document because the agency agrees with the information provided in a request from the applicant for revision of the regulatory review period.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3460.

SUPPLEMENTARY INFORMATION: In its application for patent term extension, the applicant claimed November 10, 1989, as the date the investigational new drug (IND) application for VITREON (IND 33,858) was initially submitted. FDA records showed that IND 33,858

became effective on November 10, 1989, but upon reviewing the application, FDA determined that VITREON should be regulated as a device, not a drug, and transferred the application to the Center for Devices and Radiological Health (CDRH) on April 13, 1990. The application was renumbered as an investigational device exemption (IDE) application (IDE G900050). FDA's initial determination of the regulatory review period for VITREON used April 13, 1990, as the effective date for the investigational application (63 FR 69633, December 17, 1998). However, the applicant later claimed in its request for a revision of the regulatory review period dated February 16, 1999 (Docket No. 98E–0489), that FDA's initial determination failed to take into account that the original IND became effective on November 10, 1989, because VITREON was initially considered to be a drug rather than a device. The applicant argued that FDA did not object to the November 10, 1989, submission and that November 10, 1989, should remain valid as the effective date of the investigational application because under both the IND and IDE regulations, an investigational application becomes effective 30 days after submission unless FDA notifies the applicant. Therefore, the applicant requested that the agency correct the date the investigational application became effective to November 10, 1989, the effective date of IND 33,858.

FDA reviewed its records and confirmed that IND 33,858 became effective on November 10, 1989. This application was subsequently transferred to CDRH because the agency decided to regulate the product as a device rather than a drug. Though the transfer of IND 33,858 to IDE G900050 occurred for administrative reasons the application was sufficiently complete to permit a substantive review. For this reason, FDA now accepts the date of November 10, 1989, submitted by the applicant in its request, as the date that the investigational application for VITREON became effective. Therefore, the applicable regulatory review period for the VITREON application is 2,883 days. Of this time, 757 days occurred during the testing phase of the regulatory review period, while 2,126 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: November 10, 1989. November 10, 1989, is the date that IND 33,858 became effective. The application was subsequently transferred to CDRH because FDA decided to regulate VITREON as a device rather than a drug. IND 33,858 was renumbered as IDE G900050 on April 13, 1990. This transfer occurred only for administrative reasons because IND 33,858, later designated IDE G900050, was sufficiently complete to permit a substantive review. For this reason, FDA accepts the date of November 10, 1989, as the date that a clinical investigation involving this device was begun.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: December 6, 1991. FDA has verified the applicant's claim that the premarket approval application (PMA) for VITREON (PMA P910068) was initially submitted December 6, 1991.

3. *The date the application was approved*: September 30, 1997. FDA has verified the applicant's claim that PMA P910068 was approved on September 30, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Any interested person may petition FDA, on or before September 15, 2003, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 3, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03–6226 Filed 3–14–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4815–N–12]

Notice of Submission of Proposed Information Collection to OMB; Emergency Comment Request; Grant Application Standard Logic Model; Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice of proposed information collection.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* March 31, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within fourteen (14) days from the date of this Notice. Comments should refer to the proposal by name/or OMB approval number) and should be sent to: Lauren Wittenberg, HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; e-mail: *Lauren_Wittenberg@omb.eop.gov;* fax: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov;* telephone (202) 708–2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: This Notice informs the public that the U.S. Department of Housing and Urban Development (HUD) has submitted to OMB, for emergency processing, a proposed revision to the currently approved information collection for selecting applicants for the Fair Housing Initiatives (FHIP) Program grants.

This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the